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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,986	12/08/2003	Thomas Nilsson	246424US8	2822
22850 7590 09/26/2007 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT 1616	PAPER NUMBER
			NOTIFICATION DATE 09/26/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,986	Applicant(s) NILSSON ET AL.	
	Examiner James H. Alstrum-Acevedo	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 74-95 are pending. Applicants previously canceled claims 1-43, 49, 54-55, 57, 64, and 69-70. Applicants have newly cancelled claims 44-48, 50-53, 56, 58-63, 65-68, and 71-73. Claims 74-95 are new. Receipt and consideration of Applicants' amended claims and arguments/remarks submitted on July 9, 2007 are acknowledged. Applicants' claim amendments have necessitated new rejections of the newly pending claims.

Moot Rejections/objections

All rejections and/or objections of claims 44-48, 50-53, 56, 58-63, 65-68, and 71-73 cited in the previous office action mailed on March 8, 2007 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 74-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 74 and 85 are vague and indefinite because it is unclear what would constitute the "gradual aerosolization" of the dry powder dose during delivery. The specification does not define what is meant by "gradual aerosolization" of a dry powder. Therefore, an ordinary artisan would be unable to ascertain the metes and bounds of this limitation.

The remaining claims are rejected for depending upon a rejected claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 74-75, 77-78, 79, 81-83, 84-86, 88-89, 65, and 92-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies (US 2002/0053344) for the reasons of record set forth in the office action mailed on March 27, 2006, further explained in the office action mailed on August 7, 2006, and further articulated herein below.

Response to Arguments

Applicant's arguments filed July 9, 2007 have been fully considered but they are not persuasive. Applicants traversal of the instant rejection is based on their assertions that (1) the Davies reference is allegedly the basis for the commercially available dry powder inhaler known under the commercial trademark of DISKUS[®], which according to several non-patent literature publications provided in the IDS submitted on December 5, 2006 is characterized by problems associated with the ingress of moisture due to the nature of the blister seals and (2) Davies lacks the disclosure of the gradual aerosolization of the dry powder dose during delivery. The Examiner respectfully disagrees with Applicants' traversal arguments. Regarding argument (2) this limitation is given little patentable weight because it is unclear from Applicants' disclosure,

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as set forth above in the instant office action in the rejection under 35 U.S.C. §112, 2nd paragraph, what constitutes gradual aerosolization of dry powder. Furthermore, Applicants' have provided no side-by-side comparison data demonstrating that the property of gradual aerosolization is not a characteristic of the tiotropium powder contained in the Davies medical product upon aerosolization from a dry powder inhaler (DPI). Regarding Applicants' traversal argument (1), Applicants have provided no evidence that the medical product disclosed by the Davies reference is the same medical product known under the commercial trademarks of ADVAIR[®] and DISKUS[®]. The mere visual similarity between the embodiments in the Davies' figures is insufficient to demonstrate that the Davies medical product has the same properties and problems associated with the DISKUS[®] product. The demonstration of convergent aesthetics of two different products (e.g. appearance) is not equivalent to the demonstration of convergent properties of two different products (e.g. seal properties) or lack thereof. Therefore, because the Davies reference discloses a medical product comprising a hermetically sealed container comprising a seal foil containing tiotropium dry powder (i.e. dry moisture tight container containing tiotropium), it is the Examiner's position that said medical product inherently has all the properties associated with Applicants' claimed medical product because it has the same claimed components (e.g. moisture tight seal foil).

Claims 74-82, 91-93, and 95 are rejected under 35 U.S.C. 102(e) as being anticipated by Pasbrig et al. (US 2006/0102511) for the reasons of record set forth on pages 5-7 of the office action mailed on March 8, 2007.

Response to Arguments

Applicant's arguments filed July 9, 2007 have been fully considered but they are not persuasive. Applicants' traversal of the instant rejection relies upon the same arguments presented to traverse the rejection over Davies. These arguments as applied to the disclosures of Pasbrig are found unpersuasive and the rebuttal arguments as these apply to the traversal of Pasbrig are incorporated herein by reference. Thus, the instant rejection is deemed proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 80 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2002/0053344) in view of Zierenberg, B. (WO 03/084502) for the reasons of record applied to claims 4, 15, 25, and 36 in the office action mailed on March 27, 2006, and further explained in the office actions mailed on August 7, 2006 and March 8, 2007.

Response to Arguments

Applicant's arguments filed July 9, 2007 have been fully considered but they are not persuasive. Applicants' traversal of the instant rejection relies upon the same arguments presented to traverse the rejection over Davies. These arguments as applied to the combined teachings of Davies and Zierenberg are found unpersuasive and the rebuttal arguments to the traversal of the Davies rejection under 35 U.S.C. §102(b), as these apply to the instant rejection are incorporated herein by reference. The instant rejection is deemed proper.

Claims 83 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pasbrig et al. (US 2006/0102511) in view of Caper et al. (U.S. Patent No. 5,692,496) ("Casper") for the reasons of record set forth in the office action mailed on March 8, 2007.

Response to Arguments

Applicant's arguments filed July 9, 2007 have been fully considered but they are not persuasive. Applicants' traversal of the instant rejection relies upon the same arguments presented to traverse the rejection over Davies. These arguments as applied to the combined teachings of Pasbrig and Caper are found unpersuasive and the rebuttal arguments to the traversal of the Pasbrig rejection under 35 U.S.C. §102(e), as these apply to the instant rejection are incorporated herein by reference. The instant rejection is deemed proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting cited on pages 10-17 of the office action mailed on 3/27/06 and maintained on pages 7-11 of the office action mailed on 8/7/06 over copending applications (1) 10/703,505; (2)

10/870,907; (3) 10/870,909; and (4) 10/870,945 are moot, because said copending applications have been abandoned.

Claims 74-95 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. (1) 10/603,819; (2) 10/729,024; (3) 10/834,037; (4) 10/921,192; and (5) 10/933,219 for the reasons of record set forth on pages 10-17 of the office action mailed on 3/27/06 and maintained on pages 7-11 of the office action mailed on 8/7/06.

Claims 74 and 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52 and 67 of copending Application No. 11/448,773 (copending '773) for the reasons of record set forth in the office action mailed on March 8, 2007.

Response to Arguments

Applicant's arguments filed July 9, 2007 have been fully considered but they are not persuasive. Applicants' traversal arguments of the instant rejections are that the claims in the instant application can be passed to issue to first form a firm basis for comparison. This is found unpersuasive, because the instant claims are not in condition for allowance. The rejections will be maintained at this time.

Conclusion

Claims 74-95 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

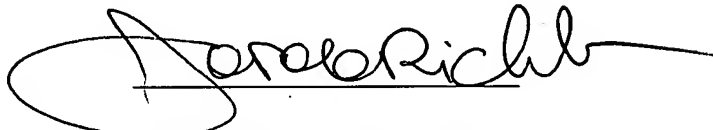
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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